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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,276	11/26/2003	Gary R. Hollenbeck	11478-008-999	1253

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,276	HOLLENBECK ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-20 and 22* is/are pending in the application.

4a) Of the above claim(s) *18-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, amendment and remarks filed 11/28/08. Claim 1 is amended. Claims 2 and 21 are canceled. Claims 18-20 and 22 are withdrawn from examination. Claims 1, 3-20 and 22 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/08 has been entered.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5, 6, 8, 13, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuna et al. ("Controlled-release liquid suspensions based on ion-exchange particles entrapped within acrylic microcapsule," in International Journal of Pharmaceutics 199 (2000), pp 151-158, provided by applicant on form PTO 1449).

Cuna discloses terbutaline-loaded ion-exchange resins where the resin is Dowex cation exchange resin of the H^+- form (abstract; paragraph 2.1-2.8) and EUDRAGIT polymer that meets the limitation of polyelectrolyte of claims 1 and 8; the dosage form contains hydroxypropylmethylcellulose meeting the limitations of the diffusion controlling membrane of amended claim 1 and claim 3 noting that claim 3 lists a number of polymers as porous diffusion controlling membrane and included in that list is a cellulose ester and hydroxypropyl methylcellulose is a specific cellulose ester. Terbutaline is cation/positively charged in the resinate since the ion-exchange resin is a cation exchange resin. The presence of polysorbate meets the limitation of dispersion agent of claim 16 and the presence of the diffusible counter ions per liter of dispersion medium as claimed in claim 13 is inherent to the composition and the Dowex ion-exchange resin is a bead, thus meeting claim 14. Cuna anticipates the designated claims.

Response to Arguments

4. Applicant's arguments filed 11/28/08 have been fully considered but they are not persuasive.

5. Applicant argues that "Cuna is silent with regard to at least three limitations of the claimed invention," namely a) that the intermediate formulation of Cuna is not suitable as a liquid form for controlled release drug composition as claimed; b) that the charged EUDRAGIT resides in the dispersed phase and not in the dispersion medium; and c) that the dispersed phase is emulsified and do not contain pharmaceutically acceptable polyelectrolyte. d) Applicant further states in footnote 2 that applicant submitted evidence to show that hydroxypropylmethylcellulose (HPMC) is a neutral polymer and not a polyelectrolyte and that

the suspension of the EUDRAGIT encapsulated terbutaline-loaded ion exchange resin in HPMC cannot meet the limitation of the applicant's claimed invention.

6. The examiner disagrees. On count d), it is noted that hydroxypropylmethylcellulose and the suspension meets the limitation of a liquid composition such that the liquid form of the composition is not just an intermediate but an end product and hydroxypropylmethylcellulose (HPMC) was not identified in the rejection as a polyelectrolyte. On count a), it is noted that the end product goal of Cuna is a controlled release liquid form (see line 2 of the abstract) so that the liquid end product form of Cuna meets the limitation of the form of the composition of the claims. For count b), a dispersed phase contains a dispersion medium so that because the dispersed phase by its very nature contains a dispersion medium and as such, the EUDRAGIT admitted by applicant to be in the dispersed phase is also in the dispersion medium. For count c), it is noted that the claims do not exclude emulsifier in the dispersed phase.

7. Therefore, while Cuna disperses the EUDRAGIT microcapsules in hydroxypropylmethylcellulose as is stated by applicant according to Cuna at paragraph 2.7, page 154, Cuna initially suspends the drug-resin particles in solution of EUDRAGIT (paragraph 2.4) and it is the EUDRAGIT that is the polyelectrolyte, which meets the requirements of the polyelectrolyte of claims 1 and 8 as stated in the rejections. Therefore, Cuna teaches and suggests a liquid form controlled release drug composition" that includes "an electrolytic drug associated with an ion exchange resin and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte having the same charge as the electrolytic drug. The comprising language of the claims is open.

Thus, Cuna anticipates amended claim 1 and the claims dependent thereon.

8. Claims 1 and 3-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Nonomura et al. (US 4,894,239) provided by applicant on form PTO 1449, (also noted is EP-0 294 103 version of the Nonomura US patent submitted by applicant on 7/30/07).

Nonomura discloses sustained release resin microcapsule preparation comprising ion-exchange resin (abstract), which dosage form is produced as oral suspension (column 4, lines 55-62) meet the requirement for liquid formulation; the ion-exchange resin is either cationic (H+ form) or anionic (OH- form) either as DOWEX or Amberlite (column 2, lines 16-23) meeting claim 14; the Dowex or Amberlite resins are of the styrene-divinyl benzene type resins meeting claims 6 and 10; when the ion exchange resin is cationic, the drug in the complex is positively charged meeting claim 5 and when the exchanger is anionic, the drug is negatively charged meeting claim 9; the composition contains water permeable polymer coat formed of natural and non-natural polymers such as ethylcellulose, aminoalkyl methacrylate copolymer or the Eudragit polymer (column 3, lines 32-42) meeting claims 1, 3, 4; the composition or dosage form contains plasticizer or antioxidant such as BHA, BHT, tocopherol or tocopherol acetate (Column 4, lines 30-36) meeting claim 16 and the additive or antioxidant and or the wetting agents or surfactants or dispersing agents (column 4, line 66 to column 5, line 8) inherently meets the limitation of claims 16 and 17; the resinate is dispersed in Eudragit (column 7, lines 22-25) meeting the limitation of polyelectrolyte (claims 8 and 12); sucrose or fructose or sorbitol or lactose when present (column 4, lines 66, 67) meets claim 15; when gelatin or xanthan gum or guar gum (column 5, lines 4-7) meeting claims 6, 7, 11, 12; the mole/liter of counter ions present in the dispersion is a property of broad dosage forms that do not recite any specific amount of the ion-exchange resin so that the dosage from of the prior art inherently anticipates claim 13; the

disclosure that the suspension is contemplated for oral administration (claim 12 and column 4, lines 55-57).

Response to Arguments

9. Applicant's arguments filed 11/28/08 have been fully considered but they are not persuasive.

10. Applicant argues that Nonomura cannot anticipate amended claim 1 and those dependent thereon because, the ion exchange resin is dispersed in the EUDRAGIT solution during an intermediate micro-encapsulation process and that the organic solvents, chloroform and cyclohexane are not pharmaceutically suitable and that examiner's indication in the advisory action that the claims do not exclude organic solvent as dispersion medium is irrelevant since the claimed composition is suitable for pharmaceutical use. But while it may be irrelevant that the claims do not exclude organic solvent, it is note worthy that applicant appears to say that those organic solvents are in an intermediate and as such not in the final form for administration that would have included the organic solvents such as chloroform and cyclohexane. Furthermore, the prior art meets the limitation of a dispersion and applicant's argument regarding how the product of Nonomura is formed is arguing against process of formation of the product of Nonomura when the claims are not directed to process of making the product. Further, the final product of Nonomura is a syrup or suspension (see column 4, line 55; column 5, lines 11 and 12; claim 12 of Nonomura) meeting the requirements for a liquid. EUDRAGIT of the intermediate as applicant would say is not removed but is present in the final product. Contrary to applicant's

statement that the final product of Nonomura does not contain a dispersion medium, it is noted that claim 1 states that the dispersion medium comprises polyelectrolyte and the polyelectrolyte EUDRAGIT in the composition of Nonomura was never removed. It is also noted that at least claim 15 says that the composition further comprises sweetening agent, flavoring agents, coloring agent and sucrose or fructose or sorbitol or lactose of Nonomura meets the limitation of claim 15 noting that sucrose or fructose or sorbitol or lactose were not identified as the polyelectrolyte.

11. Therefore, in column 7, lines 22-25, Nonomura disperses the resinate in solution of EUDRAGIT, which is one of the polyelectrolytes recited in claim 8 and thus meets the requirement that the polyelectrolyte be of same charge as the electrolytic drug. Nonomura contemplates composition that is oral suspension (column 4, lines 55-62) meeting the requirements for liquid formulation. Therefore, contrary to applicant's conclusion, Nonomura discloses a liquid formulation that is a controlled release drug composition comprising an electrolytic drug associated with an ion exchange resin (abstract; column 3, lines 10-31; column 5, line 20) and a dispersion medium comprising a pharmaceutically acceptable polyelectrolyte (column 7, lines 22-25) having the same charge as the electrolytic drug.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application Nos. 11/150,937 (US 2006/0018972) and 11/198,937 (US 2006/0134148) in view of WO 95/19184. The copending claims differ from the examined claims in that the co-pending claims do not specify what the dispersing medium is comprised of. However, the Eudragit polymers are known as dispersing according to Cohen in WO 95/19184 (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use Eudragit polymers as the dispersing polyelectrolyte in the dosage form of the examined claims.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

14. Applicant's remarks filed 11/28/08 have been fully considered but they are not persuasive.

While applicant disagrees with the above provisional obviousness type double patenting rejection, applicant is requesting that the rejection be held in abeyance because the rejection involves "pending application rather than an issued patent," applicant further requests the withdrawal of the provisional obviousness type double patenting rejection in order to assert the rejection in the pending application.

Response:

The above is not found persuasive because the provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618